



Economic Impact Analysis Virginia Department of Planning and Budget

6 VAC 35-170 – Minimum Standards for Research involving Human Subjects or Records of the Department of Juvenile Justice

Department of Juvenile Justice

June 26, 2003

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

The General Assembly allows the State Board of Juvenile Justice in §66-10 of the Code of Virginia to promulgate regulations as may be necessary to carry out provisions of Title 66 (Youth Services) and other laws of the Commonwealth administered by the director of the Department of Juvenile Justice. §66-10.1 of the Code of Virginia mandates that the State Board of Juvenile Justice promulgate regulations to implement the provisions of Chapter 5.1 of Title 32.1 regarding human research conducted or authorized by the Department of Juvenile Justice.

The proposed regulation establishes minimum requirements for research on human subjects under the care of the Department of Juvenile Justice (DJJ) and a process for the review and approval of research proposals involving human subjects. It also establishes a process for reviewing and approving research proposals on DJJ records and data that do not involve human subjects. The standards and requirements established in the proposed regulation are similar to

DJJ's existing practice for receiving, evaluating, and approving research proposals that involve human subjects and/or involve access to DJJ data.

Estimated Economic Impact

Rationale:

Prior to 1992, human research conducted or authorized by various state agencies was required to meet standards and requirements established by the Department of Mental Health, Mental Retardation, and Substance Abuse Services. In 1992, Chapter 603 of the 1992 Acts of Assembly amended the Code of Virginia to require each department that conducted or authorized human research to promulgate regulations establishing minimum standards for research on human subjects. The Code requires each agency that conducts or authorizes human research to establish a human research committee in order to ensure a competent, complete, and professional review of human research activities conducted by the agency. The committee is required to submit reports at least once a year on human research projects reviewed and approved during that year and report all significant deviations from the proposals as approved. The Code also requires that all human research projects obtain informed consent either from the person who is to be the human subject or their legally authorized representative. An exemption from these requirements is provided for certain categories of human research.

Description of the Regulation:

The proposed regulation establishes minimum requirements for research on human subjects under the care of DJJ and a process for the review and approval of research proposals involving human subjects. It also establishes a process for reviewing and approving research on DJJ records and data that do not involve human subjects.

All external research proposals are to be submitted in accordance with the requirements of the regulation. If the proposed research is to be conducted in a particular organizational unit, the proposals are to be submitted only after the researcher has obtained preliminary approval from the head of that organizational unit. Moreover, the regulation specifies information to be included in the research proposal in order for the proposal to be considered by DJJ.

Research proposals not involving human subjects are to be reviewed by designated staff members at DJJ and a recommendation for approval or denial of the proposal made to the

director of the agency within 20 days of receiving a complete research proposal. The director then has 10 days to approve or deny the proposal.

For research proposals involving human subjects, the proposed regulation prohibits experimental medical, pharmaceutical, and cosmetic research and research that involves known physical, mental, or emotional risk to the subject. For all other types of human research, the regulation establishes informed consent requirements and requirements for a human research review committee. Informed consent is to be obtained either from the person who is to be the human subject or their legally authorized representative. The human research review committee is to be set up to evaluate all human research proposals received by DJJ. The criteria to be used by the committee in evaluating research proposals are specified in the regulation. The proposed regulation also establishes reporting requirements for the human research committee. The committee is required to review all human research activities at least once a year to ensure that they are being conducted in conformance with the proposal as approved. The committee is also required to submit reports at least once a year to the Governor, the General Assembly, and DJJ on human research projects approved during the past year, the status of those projects, and any significant deviations from the proposals as approved.

For external research proposals involving human subjects, the human research review committee is required to review the proposal within 30 days of receiving it (an expedited review can be conducted under certain circumstances). The review is to include an evaluation of the research proposal in terms of the methodology used, the qualification of the researchers, and other criteria specified in the regulation. Moreover, the review is also required to include an evaluation of the informed consent procedures, including whether it can be waived or modified. Following the review, the committee is required to make a recommendation to the director of the agency to approve, deny, or conditionally approve the proposal. Based on the committee's recommendation, the director then has 10 days to approve or deny the proposal.

External researchers are also required to meet some general requirements such as having the relevant academic or professional credentials to conduct the proposed research, adhering to standards of ethics of professional societies such as the American Psychological Association, submitting a formal final report at the time of completion of the project, and possibly submitting periodic progress reports to DJJ while the project is ongoing.

The regulation also establishes confidentiality requirements for research involving human subjects and/or involving access to DJJ data, conditions for DJJ approval of research projects, and exemptions from the requirements governing human research. In addition to the Code-required exemptions, the regulation allows experimental medical treatment to be provided to subjects in the care of DJJ under certain circumstances. According to DJJ, the additional exemption allowing for experimental medical treatment is consistent with American Correctional Association standards.

Estimated Economic Impact:

According to DJJ, the proposed regulation is similar to existing requirements the agency has in place for receiving, evaluating, and approving research proposals. Following the 1992 Act of Assembly, the Board of Juvenile Justice was set up in September 1993 and the current process for reviewing and approving research projects was put in place in October 1998. DJJ believes that current requirements for reviewing and approving research projects are consistent with the requirements of other agencies such as the Department of Social Services and the Department of Mental Health, Mental Retardation, and Substance Abuse Services and consistent with the requirements of similar regulations in other states.

Each year DJJ receives approximately 20-24 research proposals involving human subjects and 60 research proposals involving the use of DJJ data.

The proposed regulation is not likely to have a significant economic impact. It is not likely to impose any additional costs on the state. DJJ already has a process in place for reviewing research proposals (including a human research review committee to evaluate research involving human subjects) and the proposed regulation simply formalizes that process. Moreover, it is not likely to impose any additional costs on researchers seeking to conduct research involving juveniles under DJJ care or involving DJJ data. The requirements of the regulation, such as consulting with the head of the organizational unit where the research is to be conducted and providing DJJ with progress reports and a final report, have been in place since 1998. To the extent that the proposed regulation, by formalizing existing practice, clarifies and leads to a more uniform application of current policy, it may produce some economic benefits.

Businesses and Entities Affected

According to DJJ, the agency receives approximately 20-24 research proposals involving human subjects and 60 research proposals involving the use of DJJ data each year. The proposed regulation is not likely to impose any additional costs on individuals seeking to do research involving juveniles under DJJ care and/or using DJJ data. To the extent the proposed regulation clarifies and standardizes existing practice, it may produce some economic benefits.

Localities Particularly Affected

The proposed regulation is not likely to have a significant impact on localities in the Commonwealth.

Projected Impact on Employment

The proposed regulation is not likely to have a significant impact on employment.

Effects on the Use and Value of Private Property

The proposed regulation is not likely to have a significant effect on the use and value of private property.